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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,098	07/18/2007	Anke Stabenau	66188NAT(50964)	6371
21874 7590 09/27/2010 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
LOVE, TREVOR M				
ART UNIT		PAPER NUMBER		
1611				
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09/27/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,098

Applicant(s)

STABENAU ET AL.

Examiner

TREVOR M. LOVE

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
4a) Of the above claim(s) 1-22, 24, 26 and 29-37 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 23, 25, 27, 28, 38 and 39 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 August 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 08/29/2008
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 09/14/2010.

Claims 1-39 are pending.

Applicant's election with traverse of Group II (a delivery system comprising a carrier and at least one active ingredient) in the reply filed on 09/14/2010 is acknowledged. The traversal is on the ground(s) that no undue search burden exists. This is not found persuasive because since a search for one group, for instance, a method of producing a delivery system according to specific steps is not coextensive with a search for a delivery system since delivery systems can be made by a plurality of methods. It is noted that Applicant has elected "dry xerogel" and "slow and controlled" release. Upon further consideration Groups IV, V, and VI have been rejoined with group II. Thus, the restriction between Groups II, IV, V and VI is hereby WITHDRAWN.

The requirement between Groups I, II (II, IV, V, VI), and III are still deemed proper, and is therefore made FINAL.

Claims 4-23 and 29-37 are currently amended. It is noted that the amendments to claims 29-31 have added an active method step, making said claims no longer be directed to a product. As such, since Applicant's elected species of Group II is a delivery system comprising a carrier and at least one active ingredient, and since if said amendment had been present at the time of restriction said methods would have been placed in a separate group, claims 29-31 are withdrawn as being directed to a non-elected invention.

Therefore, claims 1-22, 24, 26 and 29-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups and/or species, there being no allowable generic or linking claim. Election was made traverse in the reply filed on 09/14/2010. Note that claim 26 is directed to fast release, and is therefore withdrawn in view of Applicant's election of slow release.

Claims 23, 25, 27, 28, 38, and 39 are currently under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/29/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the Examiner, save for the reference lined through in view of no English translation of equivalent being provided.

Drawings

The Drawings filed 08/29/2006 have been reviewed and are accepted.

Claim Objections

Claim 23 depends from withdrawn claim 1. Applicant is required to amend claim 23 so as to remove said improper dependence.

Claim 25 depends from withdrawn claim 24. Applicant is required to amend claim 25 so as to remove said improper dependence.

Claim 27 indirectly depends from withdrawn claim 24. Applicant is required to amend claim 27 so as to remove said improper dependence.

Claim 28 depends from withdrawn claim 24. Applicant is required to amend claim 28 so as to remove said improper dependence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 25, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001).

Suverkrup teaches a pharmaceutical composition formed as a xerogel wherein said xerogel is lyophilized (freeze-dried). Said composition comprises an active compound which is dissolved and applied drop-wise to the xerogel carrier. Said composition can be hydrated with, for example, lacrimal fluid. The release of said pharmaceutical is taught to take place slowly (see entire document, for instance, column 4, lines 28-48). Said composition can be placed on strips for contact with body parts (see entire document, for instance, column 5, lines 36-48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 25, 27, 28, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001).

Suverkrup teaches a pharmaceutical composition formed as a xerogel wherein said xerogel is lyophilized (freeze-dried). Said composition comprises an active compound which is dissolved and applied drop-wise to the xerogel carrier. Said composition can be hydrated with, for example, lacrimal fluid. The release of said pharmaceutical is taught to take place slowly (see entire document, for instance, column 4, lines 28-48). Said composition can be placed on strips for contact with body parts (see entire document, for instance, column 5, lines 36-48).

Suverkrup fails to directly teach that the drops are in a pattern.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the active onto the xerogel in a regular pattern. One would have been motivated to do so to allow for the active to be evenly dispersed and allow for even access and application of the active to the environment of use. There would be a reasonable expectation of success since the use of patterns for applying actives is well known in the art, and the use of a regular pattern would further allow for greater surface area to be achieved.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23, 25, 27, 28, 38, and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-25, 27-36, 39, and 43-45 of copending Application No. 11/661,726 in view of Suverkrup et al (U.S. Patent number 6,228,381, patent issued May 8, 2001).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim recites a delivery system comprising a carrier, and active, obtainable by the method of claim 1 (namely said delivery system is a dried xerogel) which can be rehydrated, wherein the copending claims recite a dried xerogel comprising an active and carriers/excipients which can be rehydrated for use as a wound dressing.

The copending claims fail to recite that the drops comprising the active are in a pattern.

Suverkrup teaches a pharmaceutical composition formed as a xerogel wherein said xerogel is lyophilized (freeze-dried). Said composition comprises an active compound which is dissolved and applied drop-wise to the xerogel carrier. Said composition can be hydrated with, for example, lacrimal fluid. The release of said pharmaceutical is taught to take place slowly (see entire document, for instance, column

4, lines 28-48). Said composition can be placed on strips for contact with body parts (see entire document, for instance, column 5, lines 36-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the active onto the xerogel of the copending claims in a regular pattern. One would have been motivated to do so to allow for the active to be evenly dispersed and allow for even access and application of the active to the environment of use. There would be a reasonable expectation of success since the use of patterns for applying actives is well known in the art, and the use of a regular pattern would further allow for greater surface area to be achieved.

For the above identified reasons, claims 23, 25, 27, 28, 38 and 39 are directed to an invention not patentably distinct from claims 22-25, 27-36, 39, and 43-35 of commonly assigned application 11/661,726.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/661,726, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643